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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,219	07/07/2003	Christoffer Bro	BROI	7056
1444	7590	10/06/2005	EXAMINER	
BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			SCHLAPKOHL, WALTER	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 10/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/613,219	BRO ET AL.	
	Examiner	Art Unit	
	Walter Schlapkohl	1636	<i>Waf</i>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/7/2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 7-12 is/are rejected.
- 7) ☒ Claim(s) 5 and 6 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>2/10/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 1-12 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 7 is drawn to a gene coding for a mutated form of an enzyme catalyzing the conversion of glucose-1 phosphate to glucose-6 phosphate. The rejected claim thus comprises a set of genes that encompass any mutant form of an enzyme that catalyzes this reaction. This enzyme need not be a mutated form of phosphoglucomutase-2 (PGM2), since other enzymes such as AGM-1

can also substitute functionally for PGM2. The claims do not provide any structural information with regard to the sequences capable of increasing the activity of such an enzyme. Thus, the rejected claim comprises a set of enzymes that are defined by their increased catalytic activity compared to the native form.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of a complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, and any combination thereof. The specification states that "there may be present a gene coding for a mutated form of the said enzyme which mutated form has a higher specific activity than the native form of said enzyme of said microorganism" (page 6, first paragraph). The specification makes no mention of a mutant sequence or structure or form of an enzyme capable of increasing the enzyme's catalytic activity. No description is provided of such an enzyme; nor is there one example.

The prior art does not appear to offset the deficiencies of the instant specification in that it does not describe a set of mutant forms of an enzyme which increase the activity of the

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native form of an enzyme to catalyze the conversion of glucose-1 phosphate to glucose-6 phosphate. In fact, the prior art does not contain one example of such an enzyme.

Given the potentially very large genus of mutant enzymes encompassed by the rejected claims, and given the limited description provided by the prior art and specification with regard to the mutations required of any known enzyme that catalyzes the conversion of glucose-1 phosphate to glucose-6 phosphate, the skilled artisan would not have been able to envision a sufficient number of specific embodiments that meet the functional limitations of the claims to describe the broadly claimed genus of mutant genes encoding for such an enzyme. Thus, there is no structural/functional basis provided by the prior art or instant specification for one of skill in the art to envision those mutants that satisfy the functional limitations of claim 7 with regard to increased enzymatic activity such as that of PGM2. Therefore, the skilled artisan would have reasonably concluded Applicant was not in possession of the claimed invention for claim 7.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 8-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Ostergaard et al. (Nature Biotechnology 18:1283-1286) as evidenced by Oh et al (Molecular and Cellular Biology 10(4):1415-1422).

Regarding claim 1, Ostergaard et al teach two microorganisms exhibiting an increased level of galactose uptake: a GAL4-overexpressing and a Gal6/Gal80/Mig-1 deficient (both recombinant) prototrophic yeasts (*Saccharomyces cerevisiae* strains S07 and S016, respectively). These strains exhibit an increased level of galactose uptake rate (26% and 41%) when cultured on a nutrient source providing galactose (see Ostergaard, pages 1284 and Table 2). These strains inherently overexpress the activity of an enzyme catalyzing the conversion of glucose-1 phosphate to glucose-6 phosphate compared to a reference microorganism having a native level of activity when cultured in the presence of galactose as evidenced by Oh et al.

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Oh et al is cited only for the purpose of showing that phosphoglucomutase-2 is under the control of GAL4 and GAL80 when the host microorganism is cultured in the presence of galactose (see especially page 1421, first column). Thus in the yeast strains with increased GAL4 expression (S07) and decreased GAL80 expression (S016) PGM2 activity is increased compared to the wild type strain (CEN.PK 113-7D) when cultured in the presence of galactose.

Regarding claims 2-3, Ostergaard et al teach that the enzyme being overexpressed in this strain is PGM2.

Regarding claim 8, Ostergaard et al teach that both the SOC7 and S016 strains are strains of *S. cerevisiae* (see Table 2 and page 1285, second column).

Regarding claim 9, Ostergaard et al teach that the recombinant microorganisms exhibit galactose uptake rate increases of at least 10% (26% and 41%) compared to the reference microorganism (see Table 2, page 1285).

Regarding claims 11-12, Ostergaard et al teach that the yeast strains S07 and S016 exhibit increased maximum specific ethanol production of beyond a factor of 1.5 (2.0 and 2.4, respectively).

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Allowable Subject Matter

Claims 5-6 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Certain papers related to this application may be submitted to the Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is (571) 273-8300. Note: If Applicant does submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's

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Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent applications to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at (800) 786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Walter A. Schlapkohl whose telephone number is (571) 272-4439. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM. A phone message left at

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this number will be responded to as soon as possible (i.e., shortly after the examiner returns to his office.)

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached at (571) 272-0781.

Walter A. Schlapkohl, Ph.D.
Patent Examiner
Art Unit 1636

September 29, 2005



TERRY MCKELVEY
PRIMARY EXAMINER